

### **Actions Taken by FDA Center for Veterinary Medicine**

The following corrections or additions to the January 2003 list were published in the Federal Register in September 2003.

## New Approvals

**NADA Number: 141-143**

Pioneer:	113-232
Trade Name:	Tetradure™ 300, Oxytetracycline Injection 300 mg/ml
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Norbrook Laboratories, Inc.
Approval Date:	July 25, 2003
Status:	Rx for Tetradure™ 300, Over-the-counter for Oxytetracycline Injection 300 mg/ml
Route:	Intravenous, intramuscular, or subcutaneous
Species:	Cattle (beef cattle, non-lactating dairy cattle, calves including pre-ruminating and veal calves) and swine
Drug Form:	Liquid (solution)
Concentration:	300 milligrams per milliliter
Indications:	<p><b>Cattle:</b> For the treatment of pneumonia and shipping fever complex associated with <i>Pasteurella</i> spp. and <i>Haemophilus</i> spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by <i>Moraxella bovis</i>; foot-rot and diphtheria caused by <i>Fusobacterium necrophorum</i>; bacterial enteritis (scours) caused by <i>Escherichia coli</i>; wooden tongue caused by <i>Actinobacillus lignieresii</i>; leptospirosis caused by <i>Leptospira pomona</i>; and wound infections and acute metritis caused by strains of staphylococcal and streptococcal organisms sensitive to oxytetracycline. The prescription product (only) is also indicated for the control of respiratory disease in cattle at high risk of developing Bovine Respiratory Disease (BRD) associated with <i>Mannheimia (Pasteurella) haemolytica</i> and the dosage range for the treatment of pneumonia and shipping fever complex associated with <i>Pasteurella</i> spp. and <i>Haemophilus</i> spp. and infectious bovine keratoconjunctivitis (pinkeye) caused by <i>Moraxella bovis</i>.</p> <p><b>Swine:</b> For the treatment of bacterial enteritis (scours, colibacillosis) caused by <i>Escherichia coli</i>; pneumonia caused by <i>Pasteurella multocida</i>; and leptospirosis caused by <i>Leptospira pomona</i>. In sows, oxytetracycline is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by <i>Escherichia coli</i>.</p>
Tolerance:	21CFR 556.500 Oxytetracycline: Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline in tissues and in milk as follows: 2 parts per million in muscle, 6 parts per million in liver, 12 parts per million in kidney and fat.
Withdrawal:	28 days
Patent Number:	6,110,905 6,310,053
Exclusivity:	3 years
	Expiration date: August 29, 2020 October 30, 2021

21CFR 522.1660a

**NADA Number: 141-215**

Trade Name:	Equimax <sup>TM</sup>
Ingredients:	Ivermectin, praziquantel
Sponsor:	Virbac AH, Inc.
Approval Date:	July 11, 2003
Status:	Over-the-counter
Route:	Oral
Species:	Equine
Drug Form:	Paste
Concentration:	1.87 % ivermectin, 14.03 % praziquantel

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Indications: For the treatment and control of the following parasites:  
Tapeworms: *Anoplocephala perfoliata*  
Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp.  
Small Strongyles including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae): *Cyathostomum* spp., *Cylicocycclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp.  
Pinworms (adults and fourth-stage larvae): *Oxyuris equi*  
Ascarids (adults and third and fourth-stage larvae): *Parascaris equorum*  
Hairworms (adults): *Trichostrongylus axei*  
Large-mouth Stomach Worms (adults): *Habronema muscae*  
Bots (oral and gastric stages): *Gasterophilus* spp.  
Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*  
Intestinal Threadworms (adults): *Strongyloides westeri*  
Summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae.  
Dermatitis caused by Neck threadworm microfilariae, *Onchocerca* spp.

Patent Number: 5,824,653                      Expiration date: November 27, 2015  
Exclusivity: 3 years

21CFR 520.1198

### NADA Number: 141-218

Trade Name: Atopica®  
Ingredients: Cyclosporine  
Sponsor: Novartis Animal Health US, Inc.  
Approval Date: August 15, 2003  
Status: Prescription only  
Route: Oral  
Species: Dogs  
Drug Form: Capsule  
Concentration: 10, 25, 50, and 100 milligrams  
Indications: For the control of atopic dermatitis in dogs weighing at least four pounds.  
Patent Number: 5,342,625                      Expiration date: August 30, 2011  
5,741,512                                      April 27, 2015  
5,866,159                                      August 30, 2011  
5,916,589                                      March 6, 2017  
5,962,014                                      March 6, 2017  
5,962,017                                      April 27, 2015  
5,985,321                                      September 26, 2014  
6,007,840                                      March 6, 2017  
6,024,978                                      September 13, 2009  
6,262,022                                      June 25, 2012  
6,258,808                                      June 26, 2012  
Exclusivity: 3 years

21CFR 520.522



## Actions Taken by FDA Center for Veterinary Medicine

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### ANADA Number: 200-353

Pioneer Product: 091-739  
Trade Name: Primex™ Equine  
Ingredients: Pyrantel pamoate  
Sponsor: First Priority, Inc.  
Approval Date: August 19, 2003  
Status: Prescription only  
Route: Oral  
Species: Horses and ponies  
Drug Form: Liquid (suspension)  
Concentration: 50 milligrams per milliliter  
Indications: For the removal and control of mature large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equines*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles.

21CFR 520.2043

### ANADA Number: 200-357

Pioneer Product: 048-761, 128-686, 140-859, 138-935  
Trade Name: Pennchlor™ / Bio-Cox®  
Ingredients: Chlortetracycline hydrochloride, Salinomycin sodium  
Sponsor: Pennfield Oil Company  
Approval Date: August 19, 2003  
Status: Over-the-counter  
Route: Oral, via feed  
Species: Chickens (broiler)  
Drug Form: Type A Medicated Article to make Type C medicated feeds.  
Concentration: Chlortetracycline – 50 to 100 grams activity per pound of Type A Medicated Article; Salinomycin – 40 and 60 grams activity per pound of Type A Medicated Article.  
Indications: As an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.  
Tolerance: 21CFR 556.150 Chlortetracycline: Tolerances are established for the sum of residues of tetracycline, including chlortetracycline in tissues are as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in kidney and fat.  
21 CFR 556.592 Salinomycin: Not established.  
Withdrawal: 24 hours

21CFR 558.550

### ANADA Number: 200-330

Pioneer Product: 096-676  
Trade Name: Animax® Cream  
Ingredients: Nystatin, neomycin sulfate, thiostrepton, and triamcinolone acetoneide  
Sponsor: Altana Inc.  
Approval Date: September 4, 2003  
Status: Prescription only  
Route: Topical  
Species: Dogs and cats  
Drug Form: Cream  
Concentration: Each gram contains 100,000 units nystatin, 2.5 milligrams neomycin sulfate, 2500 units thiostrepton, and 1.0 milligram triamcinolone acetoneide.  
Indications: In the management of dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly those caused, complicated or threatened by bacterial or candidal (*Candida albicans*) infections.

21CFR 524.1600a

## Actions Taken by FDA Center for Veterinary Medicine

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### ANADA Number: 200-304

Pioneer Product: 012-991  
Trade Name: Pritox™  
Ingredients: Copper naphthenate  
Sponsor: First Priority, Inc.  
Approval Date: July 25, 2003  
Status: Over-the-counter  
Route: Topical  
Species: Horses and ponies (not for meat production)  
Drug Form: Liquid (solution)  
Concentration: 37.5 % w/w  
Indications: As an aid in treating thrush due to organisms susceptible to copper naphthenate.

21CFR 524.463

### ANADA Number: 200-338

Pioneer Product: 140-971  
Trade Name: Tri-Heart Plus  
Ingredients: Ivermectin, pyrantel pamoate  
Sponsor: Heska Corporation  
Approval Date: August 13, 2003  
Status: Prescription only  
Route: Oral  
Species: Dogs  
Drug Form: Tablet (chewable)  
Concentration: 68 micrograms ivermectin and 57 milligrams pyrantel; 136 micrograms ivermectin and 114 milligrams pyrantel; or 272 micrograms ivermectin and 227 milligrams pyrantel per tablet  
Indications: For the prevention of canine heartworm by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) and for the treatment and control of ascarids (*Toxocara canis*, *Toxascaris leonina*), and hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*).

21CFR 520.1196 & 510.600

### ANADA Number: 200-352

Pioneer Product: 100-237  
Trade Name: Primex™ Canine, Primex™ Canine-2X  
Ingredients: Pyrantel pamoate  
Sponsor: First Priority, Inc.  
Approval Date: August 20, 2003  
Status: Over-the-counter  
Route: Oral  
Species: Dogs and puppies  
Drug Form: Liquid (suspension)  
Concentration: 2.27 milligrams and 4.54 milligrams per milliliter, respectively  
Indications: For the removal of large roundworms (*Toxocara canis*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), including lactating bitches after whelping to prevent reinfestation of *Toxocara canis*.

21CFR 520.2043

## Actions Taken by FDA Center for Veterinary Medicine

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### ANADA Number: 200-354

Pioneer Product: 121-553  
Trade Name: Pennchlor™ / Coban®  
Ingredients: Chlortetracycline hydrochloride, monensin sodium  
Sponsor: Pennfiled Oil Company  
Approval Date: August 15, 2003  
Status: Over-the-counter  
Route: Oral, via feed  
Species: Chickens (broiler)  
Drug Form: Type A Medicated Article to make Type C medicated feeds.  
Concentration: Chlortetracycline 50, 70, 90, and 100 grams activity per pound of Type A Medicated Article, monensin 60 grams activity per pound of Type A Medicated Article.  
Indications: As an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunette*, and *E. mivati*, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.  
Tolerance: 21CFR 556.150 Chlortetracycline: Tolerances are established for the sum of residues of tetracycline, including chlortetracycline in tissues are as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in kidney and fat.  
21 CFR 556.420 Monensin: Not needed.  
Withdrawal: 24 hours

21CFR 558.355

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## Supplemental Approvals

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### NADA Number: 200-246

**This supplemental application provides for over-the-counter marketing status except when labeled for administration by stomach tube.**

Trade Name: Pyrantel Pamoate Equine Anthelmintic Suspension  
Ingredients: Pyrantel pamoate  
Sponsor: Phoenix Scientific, Inc.  
Approval Date: August 19, 2003  
Status: Over-the-counter  
Route: Oral  
Species: Horses and ponies  
Drug Form: Liquid (suspension)  
Concentration: 50 milligrams per milliliter  
Indications: For the removal and control of mature large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equines*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles.

21CFR 520.2043

## Actions Taken by FDA Center for Veterinary Medicine

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**NADA Number: 200-346**

**This supplemental application provides for an additional dose (strength) of trenbolone and estradiol implant.**

Trade Name: Component<sup>®</sup> TE-IH  
Ingredients: Trenbolone acetate, estradiol  
Sponsor: Ivy Laboratories, Division of Ivy Animal Health, Inc.  
Approval Date: August 19, 2003  
Status: Over-the-counter  
Route: Subcutaneous (ear implant)  
Species: Cattle (heifers fed in confinement for slaughter)  
Drug Form: Implant  
Concentration: Trenbolone acetate – 80 milligrams, estradiol – 8 milligrams  
Indications: For increased rate of weight gain.  
Tolerance: 21CFR 556.739 Trenbolone: Tolerance for residues is not needed.  
21CFR 556.240 Estradiol: No residues of estradiol or any of the related esters are permitted in the uncooked edible tissues in excess of the following increments above the concentrations of estradiol naturally present in untreated animals: 120 parts per trillion for muscle, 480 parts per trillion for fat, 360 parts per trillion for kidney, and 240 parts per trillion for liver.  
Withdrawal: Zero days

*21CFR 522.2477*

**NADA Number: 200-221**

**This supplemental application provides for an additional dose (strength) of trenbolone and estradiol implant.**

Trade Name: Component<sup>®</sup> TE-IS  
Ingredients: Trenbolone acetate, estradiol  
Sponsor: Ivy Laboratories, Division of Ivy Animal Health, Inc.  
Approval Date: September 3, 2003  
Status: Over-the-counter  
Route: Subcutaneous (ear implant)  
Species: Cattle (steers fed in confinement for slaughter)  
Drug Form: Implant  
Concentration: Trenbolone acetate – 80 milligrams, estradiol – 16 milligrams  
Indications: For increased rate of weight gain and improved feed efficiency.  
Tolerance: 21CFR 556.739 Trenbolone: Tolerance for residues is not needed.  
21CFR 556.240 Estradiol: No residues of estradiol or any of the related esters are permitted in the uncooked edible tissues in excess of the following increments above the concentrations of estradiol naturally present in untreated animals: 120 parts per trillion for muscle, 480 parts per trillion for fat, 360 parts per trillion for kidney, and 240 parts per trillion for liver.  
Withdrawal: Zero days

*21CFR 522.2477*

## Removal of a Patent Number

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**NADA Numbers: 135-468, 138-952, 140-926**

Patent Number: 4,665,100  
Expiration Date: May 12, 2004

## **Actions Taken by FDA Center for Veterinary Medicine**

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### **Addition of a Patent Number**

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**NADA Numbers:**     **140-942, 140-947, 141-113**

Patent Number:     4,797,275

Expiration Date:    January 10, 2006

**NADA Number:**     **140-929**

Patent Number:     5,574,020

Expiration Date:    November 12, 2013

### **Addition of Sponsor**

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Heska Corp.  
1825 Sharp Point Dr.  
Fort Collins, CO 80525  
Drug Labeler Code: 063604

### **Change of Sponsor**

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**NADA Number:**     **065-492, 065-495**

From:                Teva Pharmaceuticals, Inc.  
To:                    Delmarva Laboratories, Inc.  
                          1500 Huguenot Rd., Suite 106  
                          Midlothian, VA 23113

Drug labeler code: 059079

**NADA Number:**     **065-492, 065-495, 200-071, 200-291, 200-316**

From:                Delmarva Laboratories, Inc.  
To:                    Virbac AH, Inc.  
                          3200 Meacham Blvd.  
                          Fort Worth, TX 76137

Drug labeler code: 051311